UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/762,283	03/28/2001	Rosa Perez Gomariz	HERR 18.313	3628

26304 7590 11/01/2007

KATTEN MUCHIN ROSENMAN LLP
575 MADISON AVENUE
NEW YORK, NY 10022-2585

EXAMINER	
WEN, SHARON X	
ART UNIT	PAPER NUMBER
1644	
MAIL DATE	DELIVERY MODE
11/01/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/762,283	GOMARIZ ET AL.	
	Examiner	Art Unit	
	Sharon Wen	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09/28/2007; 10/25/2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9 and 14-19* is/are pending in the application.

4a) Of the above claim(s) *1-15,18 and 19* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *16 and 17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☒ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's amendment to the claims, filed 09/28/2007, has been entered.

Claims 10-13 have been canceled.

Claims 14-19 have been added.

Claims 1-9 and 14-19 are pending.

Election/Restrictions

2. Applicant's election with traverse of species analogue derivative of VIP in the Response to Election / Restriction filed on 07/27/2007 is acknowledged. The traversal is on the ground(s) that Ashkenazi et al. do not disclose several features of claim 1. This is not found persuasive for reasons states in the previous Restriction Requirement, mailed 08/28/2007 and reiterated herein for Applicant.

The uniting feature of the present invention is a *method for treatment of endotoxic shock in mammals comprising administration of an agent as a method of treating an inflammatory or autoimmune pathology*. Ashkenazi et al. teach a method of treating endotoxic shock in mammals comprising administering an agent, i.e. TNF antagonist (see, e.g. Abstract). As such, the uniting feature of the present application does not contribute over prior art. Therefore no special technical feature exists in the present application.

The requirement is still deemed proper and is therefore made FINAL.

3. Given newly added claims 14-19, the following species election has been set forth herein:

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

Applicant is required to elect a specific inflammatory or autoimmune pathology as recited in clams 1-15 and 17, (e.g., "endotoxic shock" OR "rheumatoid arthritis" OR "multiple sclerosis" OR "Crohn's disease" OR "implant reaction").

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the reasons stated in the previous Restriction Requirement mailed 08/28/2007 and mentioned above (see Ashkenazi et al.).

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a). The following claim(s) are generic: claim 16.

During a telephone conversation with Applicant's representative, Martha Rumore, on 10/25/2007, a provisional election was made to prosecute the species of rheumatoid arthritis. Affirmation of this election must be made by Applicant in replying to this Office action.

4. In the interest of compact prosecution, the examination has been extended to include species, vasoactive intestinal peptide (VIP).

Claims 1-15 and 18-19 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected species there being no allowable generic claim.

Claims 16-17 are currently under examination as they read on method for treating inflammatory or autoimmune pathologies administering an agent wherein the elected species of inflammatory or autoimmune pathologies is rheumatoid arthritis and the agent is VIP or an analogue derivative thereof.

Priority

5. The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent application PCT/ES00/00197). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the international application PCT/ES00/00197, as-filed, fail to provide sufficient written support in the manner provided by the first paragraph of 35 U.S.C. 112 for the newly added claim 17, in particular with the recitations of "**rheumatoid arthritis, multiple sclerosis, Crohn's disease, and implant reaction to host**".

The newly added limitation mentioned above, in Applicant's amendment, filed 08/10/2007, was not clearly disclosed in the international application PCT/ES00/00197 and would have changed the scope of the application as-filed.

It appears Applicant relies upon claims 10-13 (which have been canceled) added in the preliminary amendment, filed 03/28/2001, for support for the newly added claim limitation, "rheumatoid arthritis". However, given the **371** status of the instant application, amendments that introduce New Matter made to the international application after commencement and entry into the U.S. national phase will not be considered in a U.S. national stage application. See MPEP 1893.01(a)(3).

The domestic priority date for clam 16 is deemed the effective filing date of PCT/ES00/00197, i.e., 06/02/2000.

For a more complete discussion, see the rejection under 35 USC 112, first paragraph, New Matter.

Should Applicant disagree with the Examiner's factual determination above, it is incumbent upon Applicant to provide a showing that specifically supports the instant claim limitations.

Applicant's claim for foreign priority is acknowledged. Certified copies of foreign priority application, 9901235, submitted under 35 U.S.C. 119(a)-(d), have been placed of record in the file. The support for Applicant's claim for foreign priority cannot be determined because application 9901235 is in Spanish and no certified translation has been provided.

Drawings

6. The drawings are objected to because the labels of the graphs appear to be in Spanish (see e.g., Figure 6, Y-axis label). In addition, it is unclear whether the abbreviation "PACAP" in the figure is the same as abbreviation "ACHPA" used in the specification.

Appropriate correction is required.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

7. Applicant is requested to review the application for spelling error, the use of trademarks, embedded hyperlinks and/or other form of browser-executable code.

Trademarks should be capitalized wherever it appears and be accompanied by the generic terminology. Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Embedded hyperlinks and/or other form of browser-executable code are impermissible in the text of the application as they represent an improper incorporation by reference.

Information Disclosure Statement

8. Applicant's IDS, filed 04/16/2001, is acknowledged, and has been considered.

Claim Rejections - 35 USC § 112 first paragraph

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. *The following is a Written Description / New Matter rejection.* Given the 371 status of the instant application, amendments are not permitted to introduce New Matter into the application. See MPEP 1893.01(a)(3).

Claims 17 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Currently the newly added claims contain new matter in the recitation of "**rheumatoid arthritis, multiple sclerosis, Crohn's disease, and implant reaction to host.**"

Applicant's amendment, filed 09/28/2007, contains new matter that has been added the newly added claims. However, the specification as-filed, does not provide sufficient written description for the above-mentioned limitations.

Upon reviewing of the application PCT/ES00/00197 as-filed, the written support of the newly added limitation mentioned above is not readily apparent.

It appears Applicant relies upon the generic description of inflammatory or autoimmune diseases as disclosed in the specification as-filed on page 6 to support newly added species of diseases as mentioned above in the newly added claim limitation.

However, the specification as-filed does not appear to provide a sufficient description of a representative number of species to represent the entire genus of inflammatory or autoimmune pathologies.

Applicant's reliance on generic disclosure and possibly a single species does not provide sufficient direction and guidance to the claimed limitation as mentions above having the features currently claimed.

Furthermore, it appears Applicant relies upon claims 10-13 (which have been canceled) added in the preliminary amendment, filed 03/28/2001, for support for the newly added claim limitation, "rheumatoid arthritis".

However, given the **371** status of the instant application, amendments that introduce New Matter made to the international application after commencement and entry into the U.S. national phase will not be considered in a U.S. national stage application. See MPEP 1893.01(a)(3).

The specification as-filed does not provide written description or set forth the metes and bounds of the above-mentioned phrases. The specification does not provide blazemarks nor direction for the species of inflammatory or autoimmune pathologies encompassing the above-mentioned limitations as they are currently recited. The instant claims now recite limitations which were not clearly disclosed in the specification as-filed, and now change the scope of the instant disclosure as-filed. Such limitation recited in the present claims, which did not appear in the specification, as-filed, introduce new concept and violate the description requirement of the first paragraph of 35 U.S.C. 112.

Applicant is required to cancel the new matter in the response to this Office Action.

Alternatively, Applicant is invited to provide sufficient written support for the limitations indicated above. See MPEP 714.02 and 2163.06.

The following is a Written Description / not *New Matter rejection*

11. Claims 16-17 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the **written description** requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

There is insufficient written description of the genus encompassed by the recitation of "fragments thereof or some analogue derivative[s]" of VIP.

There is insufficient written description of the claimed genus of "fragments thereof or some analogue derivative[s]" of VIP in the absence of defining the relevant identifying characteristics such as the structure of other physical and/or chemical characteristics of the claimed genus.

The instant specification describes VIP as a regulatory peptide that modulates a wide variety of immune functions such as the phagocyte function, in each one of the stages of the process, the proliferate response, the production of immunoglobulin, the NK activity and the production of cytokines (see page 4 of specification).

However, the specification as filed does not provide written description for a genus of fragments of VIP or analogue derivatives of VIP broadly commensurate in scope with the claimed invention other than the VIP of SEQ ID NO: 1.

There is insufficient written description to lead a person of skill in the art to know which sequences are essential, which sequences are non-essential, and what particular sequence lengths identify essential sequences for identifying VIP or have the function of VIP as indicated above and disclosed in the specification as filed.

A person of skill in the art was not in possession of the breadth of claimed "fragments thereof or some analogue derivative[s]" of VIP because it was well known in the art at the time the invention was made that molecules with sequence similarity often have different functions.

For example, Attwood (Science 290: 471-473, 2000) teaches that "[i]t is presumptuous to make functional assignments merely on the basis of some degree of similarity between sequences.

Similarly, Skolnick et al. (Trends in Biotech. 18: 34-39, 2000) teach that the skilled artisan is well aware that assigning functional activities for any particular protein or protein family based upon sequence homology is inaccurate, in part because of the multifunctional nature of proteins (e.g., "Abstract" and "Sequence-based approaches to function prediction", page 34). Even in situations where there is some confidence of a similar overall structure between two proteins, only experimental research can confirm the artisan's best guess as to the function of the structurally related protein (see in particular "Abstract" and Box 2).

The Guidelines for the Examination of Patent Applications Under the 35 U.S.C § 112, paragraph 1 "Written Description" requirement make clear that the written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the genus (Federal Register, Vol. 66, No. 4 pages 1099-1111, Friday January, 2001, See especially page 1106 3rd column).

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the written description inquiry, whatever is now claimed." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.) Consequently, Applicant was not in possession of the instant claimed invention. See University of California v. Eli Lilly and Co. 43 USPQ2d 1398.

Applicant is directed to the final Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 U.S.C. § 112 is severable from its enablement provision. (See page 1115.)

Claim Rejections - 35 USC § 102

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

13. Claims 16 and 17 are rejected under 35 U.S.C. 102(a) and (b), respectively, as being anticipated by Takeba et al. (*Arthritis and Rheumatism* 1999 42:2418-2429, see entire document).

Given the New Matter recited in the newly added claim 17, this prior art reference is applicable for claim 16 under 35 U.S.C. 102(a) and claim 17 under 35 U.S.C. 102(b) as it reads on the filing date of the instant application.

Takeba et al. teach a method of treating rheumatoid arthritis with VIP (see page 2418, right column, Conclusion, and page 2428, left column, third paragraph).

Although Takeba et al. is silent on "Th1 cell inhibition", given the prior art teaching on inhibition of proinflammatory cytokine production by VIP on synovial cells from patients with rheumatoid arthritis, one of ordinary skill in the art would have recognized that the same VIP taught by the prior art would also inhibit Th1 cells when used in the same or nearly the same method of treating RA as taught by the prior art.

Products of identical chemical composition cannot have mutually exclusive properties. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. In re Spada 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). See MPEP 2112.01.

Claim Rejections - 35 USC § 103

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

15. Claims 16-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Takeba et al. (*Arthritis and Rheumatism* 1999 42:2418-2429).

Takeba et al. teach using VIP to treat rheumatoid arthritis.

The teaching of Takeba et al. differs from the claimed invention in that the reference does not exemplify treating rheumatoid arthritis by administering VIP.

However, given the reference suggestion on the anti-inflammatory effects of VIP maybe applicable in the treatment of patients with RA (see page 2428, left column, third paragraph), one of ordinary skill in the art, upon reading the reference, would have recognized the desirability of treating RA with VIP.

The Takeba reference also inherently disclose to one of ordinary skill in the art that VIP has therapeutically effective property on RA given its ability to inhibit proinflammatory cytokine production in synovial cells from patients with rheumatoid arthritis (see page 2418, right column, first full paragraph).

Thus it would have been obvious to a person or ordinary skill in the art, at the time of invention, to try the method of administering VIP in patient with RA as taught by the prior art, as a person with ordinary skill has good reason to pursue the known options within his or her technical grasp.

In turn, because administration of VIP as claimed has the function of treating RA as predicted by the prior art, it would have been obvious to treat RA comprising administering VIP.

Therefore, the invention, as a whole, was *prima facie* obvious to one of ordinary skill in the art, at the time the invention was made as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion

16. No claim is allowed.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharon Wen whose telephone number is (571) 270-3064. The examiner can normally be reached on Monday-Thursday, 8:30AM-6:00PM, ALT. Friday, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571)272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Sharon Wen Ph.D.
Patent Examiner
October 25, 2007

PHILLIP GAMBEL, PH.D . JD.
PRIMARY EXAMINER
TC 1600
10/19/07